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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

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TITLE OF THE INVENTION (280 characters max)

IN-VIVO SENSING DEVICE WITH DETACHABLE PART

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ENCLOSED APPLICATION PARTS *(check all that apply)*

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☐ Application Data Sheet. See 37 CFR 1.76 ☒ Other (specify) postcard

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT *(check one)*

☐ Applicant claims small entity status. See 37 CFR 1.27.

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Respectfully submitted,

Date 31 / Dec / 2003

SIGNATURE

REGISTRATION NO. *(if appropriate)* 37,912

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USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

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UNITED STATES PROVISIONAL PATENT APPLICATION

IN-VIVO SENSING DEVICE WITH DETACHABLE PART

FIELD OF THE INVENTION

The present invention relates to the field of in vivo sensing. Specifically, the present invention relates to a floatable in vivo sensing device with a detachable part.

BACKGROUND OF THE INVENTION

An in vivo device such as an ingestible sensing device may be used for sensing in vivo conditions in cavities or body lumens such as for example the gastrointestinal (GI) tract. Parameters that may be sensed or detected include for example temperature, pH, pressure, electroconnectivity, etc. In-vivo imaging devices may be used for imaging of body lumens such as the GI tract. For example, an ingestible capsule comprising a sensor, such as an image sensor, may be ingested and may move through the small intestine by peristalsis while imaging or otherwise sensing the small intestine. However, passive movement of objects such as for example imaging sensors, such as by way of peristalsis through larger body lumens, such as the large intestine, may be slow and unpredictable and may not facilitate proper imaging of such larger body lumens.

An essentially floatable in vivo sensing device may float in or be carried by liquids in for example a body lumen. Such sensing device may be useful in sensing, such as by imaging, lumens containing or capable of containing a bulk of liquid. One example of such a lumen is the large intestine or colon. A floatable sensing device may be carried by the liquid in the large intestine and may thus be moved through the lumen together with the bulk of liquid.

The large intestine or colon, whose main function is to remove much of the water from the stool and to store the stool, begins with the cecum, a small saclike

evagination, then continues with the ascending colon, from the appendix in right groin up to a flexure at the liver, transverse colon, liver to spleen, descending colon, spleen to left groin, then sigmoid (S-shaped) colon back to midline and anus. The colon has three longitudinal muscle bands whose actions assist movement through the colon.

It may be advantageous to move objects through the colon independently of the natural action of the colon muscles. For example, delivery of a medicament to a specific location in the colon may be time dependant, such that the natural movement in the colon may not be sufficiently reliable to deliver such medicaments on time. Also a device for imaging the colon might benefit from being moved, such as by way of floating, through the colon so as to efficiently view the colon.

While a floating in vivo sensing device may be useful in lumens with a bulk of liquids such as for example in certain parts of the colon, a floating in vivo sensing device may be less than optimal for sensing of other areas of the GI tract, such as for example the small intestine. Furthermore, a floating in vivo sensor typically traverses the GI tract relatively slowly. Thus, an internal power supply (e.g., a battery) may be depleted before the floatable sensor reaches the end of the GI tract.

There is therefore a need to facilitate the traverse of a floatable in vivo sensing device.

SUMMARY OF THE INVENTION

Embodiments of the invention may be for example floatable or have a certain buoyancy or specific gravity in some parts of a lumen and be non-floating or have a certain other buoyancy or specific gravity in other parts.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be understood and appreciated more fully from the following detailed description taken in conjunction with the drawings in which:

Fig. 1 is an illustration of an in vivo sensing device with a detachable heavy part and a light part in accordance with an exemplary embodiment of the invention;

Fig 2. is a schematic illustration of an area of an in vivo sensing device where a heavy part and a light part of such device may be connected in accordance with an exemplary embodiment of the invention;

Fig. 3 is a schematic illustration of an in vivo device with a switch and a detachable part in accordance with an exemplary embodiment of the invention;

Fig. 4 is a schematic illustration of an in vivo device with at least one sensor, a switch and a detachable part in accordance with an exemplary embodiment of the invention; and

Fig. 5 is a flowchart schematically illustrating a method for in vivo sensing of a lumen, according to an embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

In the following detailed description, numerous specific details are set forth in order to provide a thorough understanding of the invention. However, it will be

understood by those skilled in the art that the present invention may be practiced without these specific details. In other instances, well-known methods, procedures, and components have not been described in detail so as not to obscure the present invention.

According to some embodiments of the present invention, there is provided an in-vivo sensing device that may be configured to for example alter configurations so that at a particular times or in some areas or body lumens, such as for example the small intestine, it may be or include a floating or buoyant device, while at other times or at other areas or body lumens such as for example parts of the large intestine, it may be a non-floating device.

In some embodiments, a sensing device in accordance with an exemplary embodiment of the invention may be an ingestible sensing device. Embodiments of an ingestible imaging device are described in US Patent No. 5,604,531 to Iddan et al. and in International Application publication number WO 01/65995, entitled "A Device And System For In Vivo Imaging", published on 13 September, 2001, both of which are assigned to the common assignee of the present application and incorporated herein by reference. Embodiments of a floatable sensing device are described in US Patent Application number 10/150,492, which was published under the publication number 20030018280 on January 23, 2003 and which is assigned to the assignee of the present invention and which is hereby incorporated by reference. Various embodiments of the present invention may use devices and methods, such as imaging and/or receiving devices and methods, as described in US 5,604,531 and/or WO 01/65995 and or US 20030018280, however other embodiments may use methods and have structures not found in these references.

Reference is now made to Fig. 1, an illustration of an in vivo sensing device with a detachable heavy part and a light part, in accordance with an exemplary

embodiment of the invention. Device 10 may be a sensing device such as for example an autonomous in-vivo imaging device. In some embodiments device 10 may include for example other sensors instead of or in addition to an imaging sensor, such as for example a temperature sensor, a pH sensor, a pressure sensor or an electrical conductivity sensor. Other sensors are possible. For example, a motion detector may be included in device 10 for determining, for example, when the device is not in motion; external motion detection may be used as well.

In some embodiments device 10 may include for example an optical window 21 and an imaging system for obtaining image data from inside a body lumen. The imaging system may include for example one or more illumination sources 23, such as for example a white LED or another illumination source that may illuminate in another color or use some other electromagnetic frequency. Device 10 may for example include an imager such as for example an imager 24, which may detect images, and an optical system 22, which may include, for example, a lens and a lens holder, which may for example focus images onto the imager 24. In one embodiment, imager 24 is a CMOS imager, however, other types of imagers such as for example a CCD may be used. Illumination source 23 may illuminate for example a body lumen through optical window 21. Device 10 further may include circuitry such as for example an ASIC transmitter/controller 26 and an antenna 27 that may for example transmit signals, and a power source 25, such as for example silver oxide batteries, that may for example provide power to the electrical elements of device 10. Signals that may be transmitted by for example ASIC transmitter/controller 26 may include video, still image, temperature, pH or other sensory data as may be collected by device 10. Other components, sets of components or configurations may be used or included in device 10.

Device 10 may be shaped as a cylinder with convex ends, as a sphere or in other shapes or dimensions as may be suitable for passage in or through a body lumen. Device 10 may in some embodiments be shaped as an oval or capsule. Other shapes may be used.

In some embodiments, device 10 may be configured for example in two or more lobes or parts, which may be releasably held together such that such parts may be detached for example under certain conditions or upon the occurrence of certain events. One of such parts may for example be a floating, buoyant or light part 12 and another may be a non-bouyant or heavy part 30. In some embodiments, the terms light and heavy may be relative terms with respect to buoyancy and not necessarily with respect to the absolute weight of a light part 12 as compared to a heavy part 30. In some embodiments light part 12 may be releaseably connected to heavy part 30 so that heavy part 30 is detachable from light part 12. In some embodiments, light part 12 may include or contain some or all of the device's 10 sensors such as optical system 22, as well as the device's 10 ASIC transmitter/controller 26, power source 25 and antenna 27, such that for example light part 12 may be self contained, being capable of performing sensory and transmitting functions after it detaches from heavy part 30. In some embodiments, heavy part 30 may also include for example one or more sensors 33 such as for example an imager, a pH sensor, a thermometer or other sensor, and a power source 32 such as for example a battery, so that heavy part 30 may for example perform sensing functions before or after it detaches from light part 12 or independently of light part 12. In some embodiments sensor 33 may be linked by for example wires 35 or other circuitry to the ASIC transmitter/controller 26 and antenna 27 of light part 12 so that sensory data collected by heavy part 30 may be transmitted through antenna 27 while heavy part 30 and light part 12 are attached. In some embodiments, heavy part 30 may include a

transmitter and circuitry 34 so that it may broadcast sensory data after it is detached from light part 12.

Heavy part 30 may be configured to have a specific gravity above 1 and/or a specific gravity which renders it non floatable. Typically, according to some embodiments of the inventions when heavy part 30 is connected to or attached to light part 12, device 10 is not generally buoyant or floatable in water or other fluids as may be present in for example a body lumen such as for example the GI tract. Heavy part 30 may, in some embodiments, be weighted with weights 31 of for example metal, plastics or some other suitable material. The size of heavy part 30 may in some embodiments be up to approximately one third the size of device 10, though other sizes and ratios are possible.

Light part 12 may be weighted or configured to have a specific gravity of less than or approximately 1 in water or other fluids found in a body lumen, such that light part 12 (typically without heavy part 30 attached to it) may float in body fluids or other fluids, such as water. In some embodiments light part 12 may be weighted for example evenly around one or more of its internal axis so that when it floats in a liquid it may not favor a particular orientation, but may rotate or otherwise move relatively freely in surrounding water or other fluids. In some embodiments, light part 12 may be weighted to favor a particular orientation so that it may for example return to a favored orientation even after it is moved or rotated away from such favored orientation.

In some embodiments and in an initial state when for example device 10 may be ingested or otherwise inserted into a body, light part 30 and heavy part 12 may be attached to each other and device 10 may therefore assume a non-buoyant configuration. In some embodiments, device 10 may be propagated or moved passively by way of

peristalsis or otherwise through a body lumen such as for example the stomach or small intestine, in such non-buoyant configuration.

In some embodiments, at a particular time, or at a particular point in a body lumen or in response to for example a signal, environmental condition or the passage of time, light part 12 may separate or detach from heavy part 30 and assume a buoyant or floating configuration. In some embodiments the detaching of light part 12 from heavy part 30 may occur or be initiated for example at or near the point where device 10 approaches or enters the cecum, a small sac-like formation before the colon. Other points for such detaching or release may be designated. In some embodiments, the configuration, weight or specific gravity of device 10 before heavy part 30 is detached from light part 12 may cause device 10 to settle for example in or near the secum, where the detachment of heavy part 30 from light part 12 may take place.

A detached heavy part 30 may in some embodiments continue sensing or collecting data and possibly transmitting data to an external receiving system. In some embodiments detached heavy part 30 may be excreted from a body by natural or other processes.

Reference is made to Fig. 2, a schematic illustration of an area of an in vivo sensing device where a heavy part and a light part of such device may be connected. In some embodiments, light part 12 and heavy part 30 may be attached for example along a plane 200 which may in some embodiments be near or include an end or pole of light part 12. Plane 200 which may be for example along the edge of light part 12, may in some embodiments be convex so that when heavy part 30 is detached from light part 12, light part 12 assumes or retains a capsule or oval shape. Plane 200 along the edge of heavy part 30 that may be close to light part 12 may be concave or in a half moon shape so that is fits smoothly into light part 12. Other shapes such as for example a wave that

alternates between convex and concave, are possible and other planes along which heavy part 30 and light part 12 may be attached are possible.

Heavy part 30 and light part 12 may be attached or releasably held together by a fastening means 202 such as for example glue, fuses, wires, magnets or other fastening means or combination of fastening means that may releasably hold and then later release heavy part 30 from light part 12. Releasably holding may mean for example holding an item until such time as the hold is released or until a trigger, event or condition facilitates the release of the item.

In an exemplary embodiment of the invention, fastening means 202 may be freed or may release a releasably held item such as for example heavy part 30, in response to for example a signal, in response to the passage of time or in response to environmental conditions. For example, fastening means 202 may be or include a wire or filament such as for example a fuse or heat sensitive or degradable filament. In some embodiments, in response to a signal, heat may be applied to or a current may be passed through fastening means 202 such as for example a heat sensitive filament or fuse, and heat sensitive filament or fuse may melt or degrade, freeing or allowing the detaching of heavy part 30 from light part 12. In some embodiments heat, an electrical charge or other force may be applied to a fastening means 202 by for example wires 204 connected to power source 32 or power source 25 or some other power supply.

In some embodiments fastening means 202 may be for example one or more magnets, magnetized materials or materials that are responsive to magnets. Upon or in response to a signal, or at other times, such magnets may be deactivated or otherwise released, by for example reversing the polarity of a magnet, thereby freeing or detaching heavy part 30 from light part 12.

In still other embodiments, fastening means 202 may be a degradable filament or glue that may degrade over the course of for example the several hours or other time period in which device 10 may be in a body before it reaches a designated body lumen such as for example the large intestine. In some embodiments such period may be from 6 to 8 hours. Such degradation may be precipitated by for example exposure to body temperatures, exposure to certain liquids, pH levels or other elements or conditions as may be present in a body lumen. In some embodiments the thickness or other characteristics of a fastening means 202 such as for example a degradable filament or glue may be configured to degrade over a period of time that may approximate the period required for device 10 to travel or be moved from for example the mouth to for example the cecum or some other location. Other configurations are possible and other time periods or degradation triggers or criteria may be used.

Other methods or processes for releasing fastening means 202 such as for example by the release of a chemical that may degrade fastener 202, from for example a portion of light part 12 or heavy part 30 along for example plane 200, are possible. In some embodiments, heavy item 30 or light item 12 may encapsulate medicaments or other materials that may be released when heavy part 30 detaches from light part 12.

The detaching of heavy part 30 from light part 12 may in some embodiments be precipitated or initiated by for example a signal. In some embodiments, a signal may be generated by for example circuitry 34 or ASIC transmitter/controller 26. In some embodiments, a signal may be generated for example in response to a timer 208 or counter that may be included in for example circuitry 34 or ASCI transmitter/controller 26 or elsewhere, and such timer may be set to generate a signal after for example the lapse of time that may approximate the amount of time required for device 10 to proceed from for example the mouth to for example the cecum. Other time periods are possible.

In some embodiments timer 208 may be activated when for example device 10 is ingested or when for example device 10 is removed from its packaging prior to ingestion.

In some embodiments a signal may be initiated from a source external to device 10 such as for example a transmitter located outside of a body. Such signal may be received by or may otherwise affect a component of device 10. For example, device 10 may include a receiver 206 that may receive a signal from a transmitter outside of a body. Such receiver 206 may initiate for example a pulse of heat, electricity or magnetic charge to release fastening means 202, thereby detaching heavy part 30 from light part 12. In other embodiments a signal may be generated by, for example, an ultrasound mechanism that may be located outside of a body and that may direct ultrasound waves towards a fastening means 202, such as for example a filament that is sensitive to ultrasound waves. Other signals that may precipitate a release of fastening means 202 and the detaching of heavy part 30 and light part 12 are possible. In some embodiments ultrasound waves may be directed at device 10 or heavy part 30 and such ultrasound waves may detach or otherwise break apart heavy part 30.

In some embodiments the sensors or sensing devices of device 10 may, until heavy part 30 separates from light part 12, be inactive, set to off or may operate at a reduced rate or under reduced power consumption levels. In an exemplary embodiment, the detachment or separation of heavy part 30 from light part 12 may trigger or serve as a signal for device 10 to activate or turn on, or for one or more sensors of light part 12 to begin collecting sensory data such as for example images. The turning on of device 10 or of sensors in light part 12 that may begin for example with the separation or detachment of heavy part 30, may for example preserve the power available to light part 12 in, for example, power supply 25 so that sufficient power remains in such power

supply 25 or in light part 12 to power sensors and collect sensory data from body lumens, such as for example some or all of the large intestine wherein light part 12 may be set afloat.

Reference is made to Fig. 3, a schematic illustration of an in vivo device with a photodiode switch and a detachable portion in accordance with an exemplary embodiment of the present invention. The device 10 depicted in Fig. 3 may include a switch 300 such as for example a photodiode switch on or near plane 200 and an illumination device 302 such as for example a light emitting diode (LED) which may also be situated on or near, and facing plane 200. In some embodiments switch 300 may be situated in light part 12 and illumination device 302 may be situated in heavy part 30. In other embodiments, switch 300 and illumination device 302 may be situated elsewhere in device 10 and may be connected to for example power source 32 or power source 25. In some embodiments, plane 200 may be made for example from a transparent material or may otherwise be transparent or semi-transparent to the light emitted by illumination device 302.

In some embodiments, in response to a signal such as for example a signal from a counter such as for example timer 208 or some other counter or some other signal, illumination device 302 may emit light or otherwise signal switch 300 with for example light that may be detected by switch 300. Such signal as received by switch 300 may trigger, activate or otherwise turn on one or more sensing devices or other components of light part 12 or device 10. A counter such as for example timer 208 may also signal a power source such as for example power source 25 or power source 32 to provide a pulse of for example, heat or electricity that may release or burn fastening means 202 such as for example wires, fuses or filaments, thus detaching heavy part 30 from light part 12.

Reference is made to Fig. 4, a schematic illustration of an in vivo device 400 with one or more sensors, a photodiode switch and a detachable part in accordance with an exemplary embodiment of the invention. Device 400 may be an in vivo sensor that includes a detachable lobe, such as a heavy part 404, and a light part 402. Light part 402 may include one or more sensors such as for example imaging sensors which may be located for example on opposing ends or sides of light part 402. Other or additional sensors may also be included, and sensors may be situated on other parts of light part 402. One or more sensors such as for example imaging sensors in light part 402 may include one or more illumination elements 406 and an optical imaging system that may include for example a lens 408 and an imager 410 such as for example a CMOS imager. Light part 402 may in some embodiments also include a counter 412 that may include for example a timer. Counter 412 may be capable of tracking the time that has elapsed since a certain event such as for example the introduction of device 400 into a body or some other event. Counter 412 may be connected to illumination device 406 or other components of device 400 by for example wires 411 or other circuitry. In alternate embodiments wireless communication is possible between different components within device 400.

In some embodiments, heavy part 404 of device 400 may be attached to light part 402 by way of for example fasteners 414. Fasteners 414 may be, include or rely upon for example wires, fuses, such as for example burnable fuses, filaments, such as for example degradable filaments, glue, magnets or other items that may detachably or releasably hold heavy part 404 onto for example a fixed position of light part 402. Heavy part 404 may in some embodiments include a power source 416 such as a battery or other power source, a switch 418 that may be part of or included in for example a photodiode sensor or other light-sensitive sensor, and wiring 420 that may connect or

link power source 416, switch 418, fasteners 414 or other components. Alternatively, the components may be connected through a wireless connection, such as by microwave.

In some embodiments, a signal may be generated by for example counter 412, and such signal may activate for example one on more of illumination devices 406. Illumination devices 406 such as for example those that face heavy part 402 may have been off or inactive until such signal was generated. In response to a signal, one or more of illumination devices 406 may emit light. Such light may be detected by for example a photosensitive sensor or switch 418. In response to the light that it detects, for example from illumination device 406, switch 418 may signal for example power source 416 to apply for example heat, electricity or some other force to release fasteners 414. The release of fasteners 414 may detach or free heavy part 404 from light part 402.

In some embodiments the signal from for example counter 412 or some other source may be generated in response to the passage of time, such as for example the passage of the approximate time that may lapse between the ingestion of device 400 and its arrival at a particular body lumen or organ such as for example the colon or cecum (e.g., 6-8 hours from ingestion). In other embodiments, a signal may be generated in response to other events or stimulus that may occur or be provided from inside device 400 or from sources external to device 400.

According to some embodiments of the invention there is provided a method for sensing a lumen such as, for example, the large intestine. A method according to one embodiment is schematically described in Fig. 5. In one embodiment an in vivo sensing device which includes, for example, a floatable part and a non floatable part which may be releasably connected, is inserted into a patient's GI tract (502), typically by ingestion. The in vivo sensing device - according to one embodiment, an imaging device— may be activated or not upon ingestion. According to some embodiments, activation of the

device may be done, for example, as described above. After a time period which may be indicative of the device having arrived at the patient's cecum (e.g., 6-8 hours after ingestion) the floatable and non floatable parts may be caused to become detached from each other (504). According to some embodiments a signal is generated which causes the two parts to become detached. According to some embodiments the detachment may be caused in response to indications other than time. For example, a motion detector, which may be included in the device, may indicate, by showing the device is not in motion, that the device has arrived in the cecum and a signal may then be generated to cause detachment. Other suitable destinations or marker points, other than the cecum, may be used. Further, other lumens, other than the large intestine, may be targeted. Upon detachment of the two parts the floatable part, which may include in vivo sensing capabilities, may be activated (506) thus enabling the floatable part, which will be easily transported through at least parts of the large intestine, to sense (e.g., in one embodiment image) the large intestine. In alternate embodiments, other parts, such as a non-floatable part, may be activated for sensing.

While the invention has been described with respect to a limited number of embodiments, it will be appreciated that many variations, modifications and other applications of the invention may be made which are within the scope and spirit of the invention.

CLAIMS

I claim:

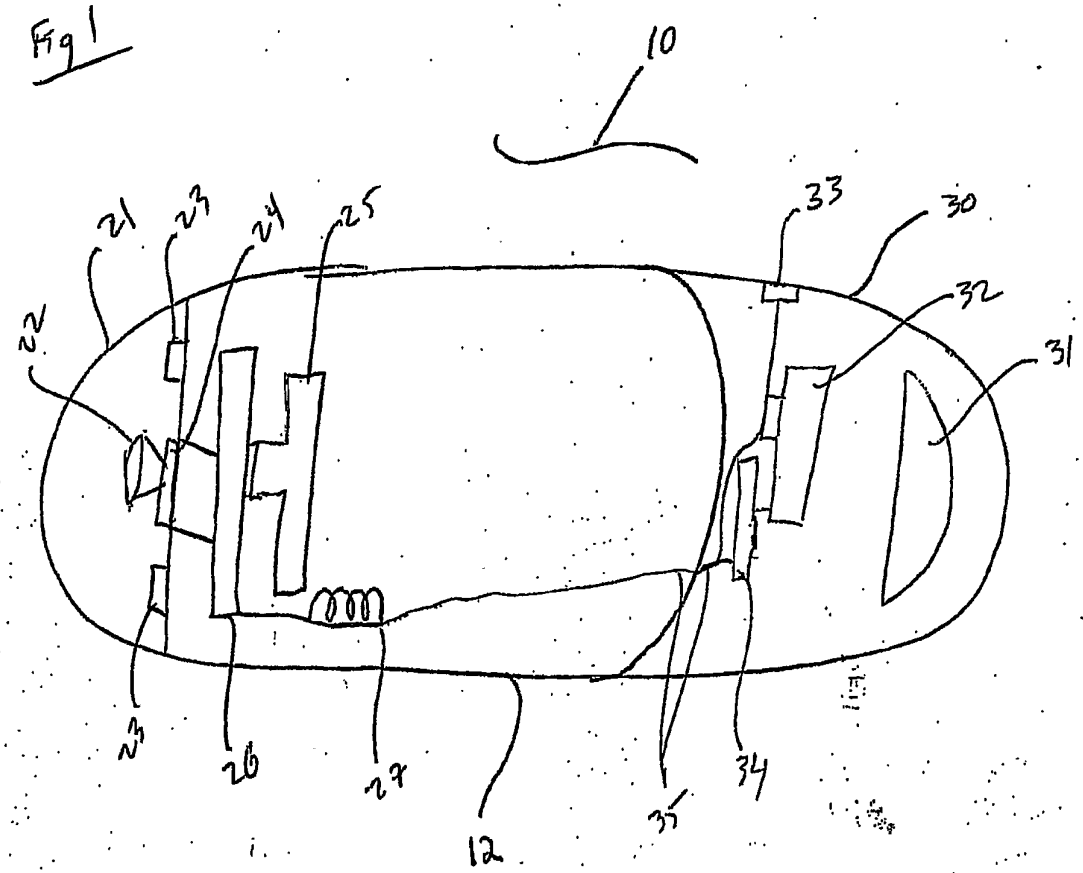
1. A device substantially as described hereinabove.

2. A device substantially as illustrated in the drawings.

3. A method substantially as described hereinabove.

4. A method substantially as illustrated in the drawings.

Fig 1



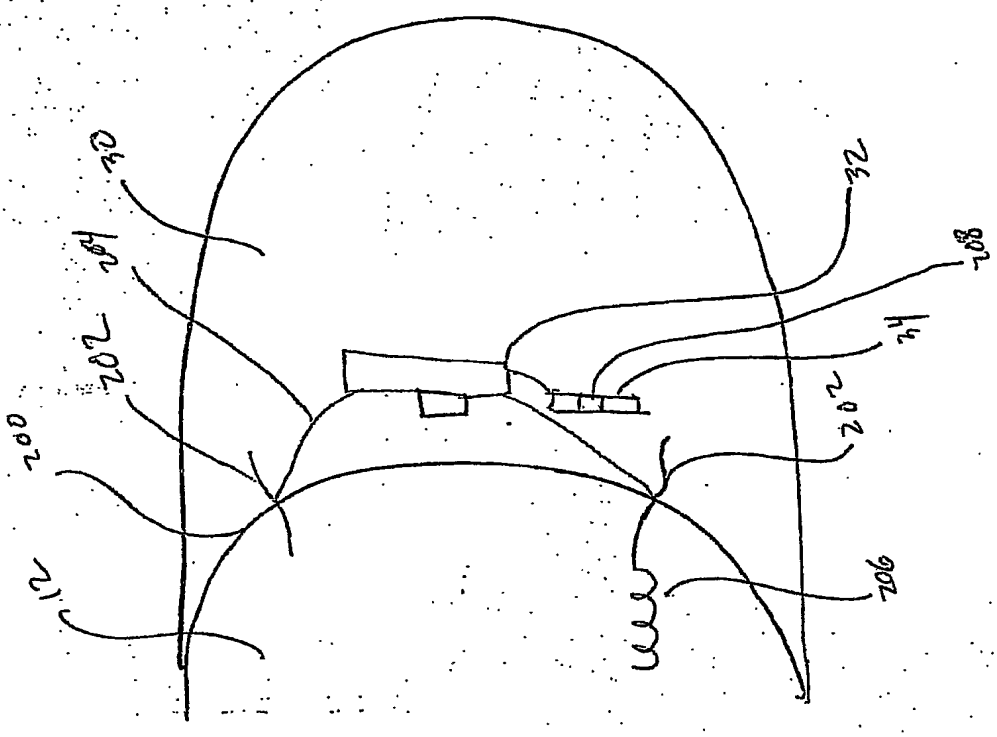


Fig 2

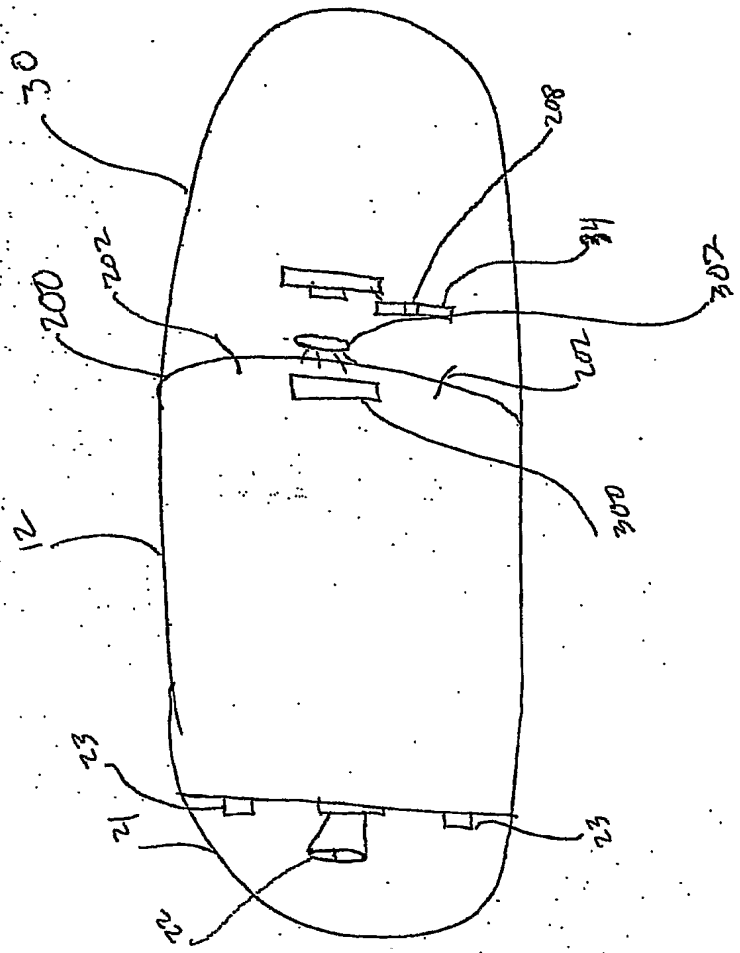


Fig 3

Fig 4

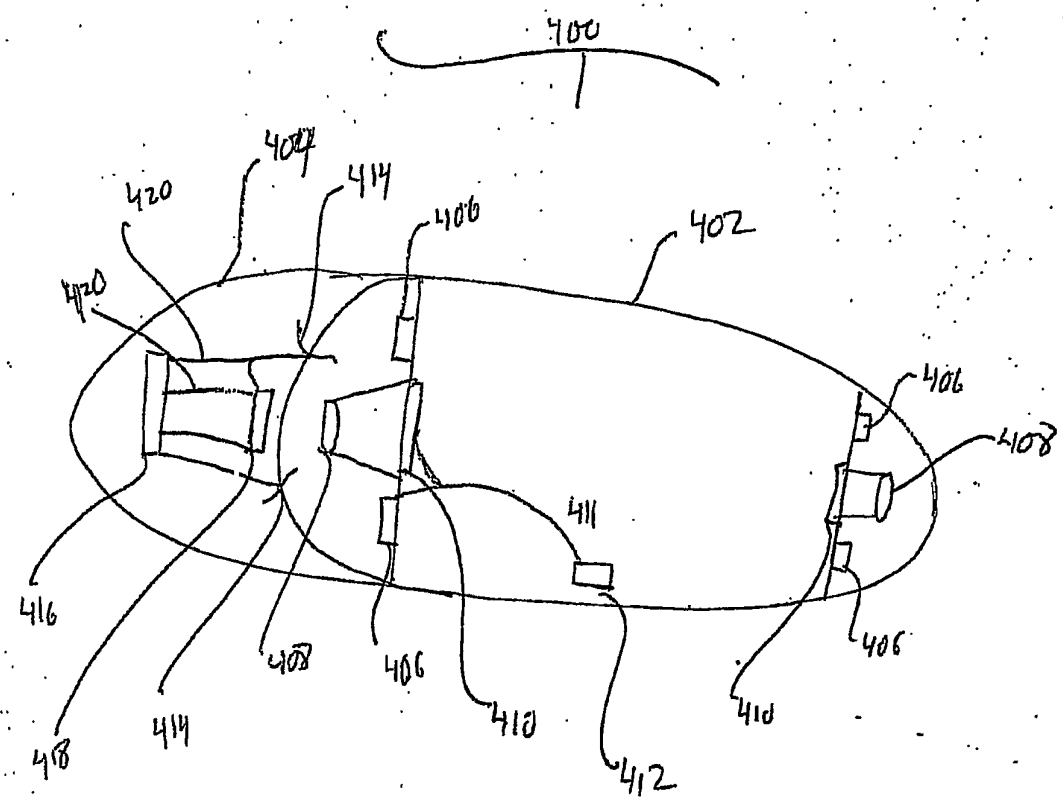


Fig 5